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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/759,904

01/16/2004

Eric J. Beckman

02-012

1518

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EXAMINER

ROGERS, JAMES WILLIAM

ART UNIT

PAPER NUMBER

1618

MAIL DATE

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07/02/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/759,904	Applicant(s) BECKMAN ET AL.	
	Examiner JAMES W. ROGERS	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 April 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-103 is/are pending in the application.
- 4a) Of the above claim(s) 13-14, 17, 27-68 and 70-103 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3-12, 15, 16, 18-26 and 69 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants amendments to the claims filed 04/30/2008 have been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 12 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically claim 12 does not further limit claims 1 or 7 since claim 1 already recites that the multifunctional isocyanate is derived from an aliphatic compound, thus the claim is indefinite with respect as to how the claim is further limiting claims 1 and 7. This new rejection was necessitated by applicant's amendments to the claims.

Response to Arguments

Applicant's arguments, see Applicant Arguments/Remarks Made in an Amendment, filed 04/30/2008, with respect to the 102(b) rejection over Chen have been fully considered and are persuasive, Chen does not teach using an aliphatic diisocyanate as now required by applicants claims. The rejection over Chen has been withdrawn.

Claims 1,3,7-8,10-12,19-22,27,34-35 and 69 are rejected under 35 U.S.C. 102(b) as being anticipated by Lipatova et al. (Macromol. Symp. 152,139-150 (2000)), for the reasons set forth in the previous office action filed 11/30/2007.

Applicant's arguments filed 04/30/2008 have been fully considered but they are not persuasive.

Applicants assert that Liptova discloses specifically only toluene diisocyanate (TDI) and does not teach the use of a multifunction isocyanate derived from an aliphatic compound. Applicants further assert that there is no disclosure within Liptova of release of heparin or any other bioactive agent within a living organism and applicants further assert that heparin is not likely to be released upon degradation of the polyurethane.

The examiner respectfully disagrees with the above assertions by applicants. Firstly Liptova clearly teaches the use of aliphatic diisocyanates such as hexamethylene diisocyanate (HDI). Regarding applicant's assertion that it would be impossible to determine if heparin would be a degradation product and if it would be released into the body, since Liptova anticipates applicants claimed composition the examiner assumes that it must be capable of biodegrading and releasing the bioactive within a living organism. Besides the recitation that the polyurethane composition releases a bioactive agent within the body by degradation is an intended use type of limitation for the composition. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Claims 1,3-12,15-16,19-20,22,25 and 69 are rejected under 35 U.S.C. 102(e) as being anticipated by Beckman et al. (US 7,264,823 B2), for the reasons set forth in the previous office action filed 11/30/2007.

Applicant's arguments filed 04/30/2008 have been fully considered but they are not persuasive.

Applicants assert that the adhesives of Beckman are formed in the absence of water as shown by the examples, which is in contrast to applicant's claimed invention which requires that the multifunctional isocyanate compound are reacted with at least one bioactive agent in solution with water.

The relevance of these assertions is unclear. Firstly as mentioned by applicants response Beckman's adhesives have isocyanate groups that reacts with tissues and **moisture** in the surrounding tissue, thus it would appear that the adhesive is reacted with water. Secondly the examples within Beckman were given solely for the purpose of illustration and were not to be construed as being limiting to their invention since many variations are possible without departing from the spirit and scope of the invention. However the facts above are of little concern since applicants attempted limitation that the isocyanate compound and bioactive agent are reacted in a solution with water is a product by process type of limitation. Applicants claims are drawn to a polyurethane composition, thus the process to make the polyurethane does not lead to a patentable distinction from the prior art, therefore since the product produced in Beckman is the same as applicants claimed invention the limitations are considered met. "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even

though the prior product was made by a different process.” In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

Claims 1,3-4,7-8,12,19,22,27-30,33 and 69 are rejected under 35

U.S.C. 102(e) as being anticipated by Woodhouse et al. (US 6,221,997 B1), for the reasons set forth in the previous office action filed 11/30/2007.

Applicant's arguments filed 04/30/2008 have been fully considered but they are not persuasive.

Applicants assert that Woodhouse's polyurethanes are formed in the absence of water, which is in contrast to applicant's claimed invention which requires that the multifunctional isocyanate compound is reacted with at least one bioactive agent in solution with water. Applicants further assert that water is considered as a contaminant that would negatively impact the mechanical properties of the polyurethanes of Woodhouse.

The relevance of these assertions is unclear. As stated above in the response for Beckman applicant's attempted limitation that the isocyanate compound and bioactive agent are reacted in a solution with water is a product by process type of limitation. Applicants claims are drawn to a polyurethane composition, thus the process to make the polyurethane does not lead to a patentable distinction from the prior art, therefore since the product produced in Wodhouse is the same as applicants claimed invention the limitations are considered met.

Claims 1,3-12,15-16,18-26 and 69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhang et al. (Biomaterials 21 (2000) 1247-1258) in view of Liptova et al. (Macromol. Symp. 152, 139-150 (2000)) or in view of Woodhouse et al. (US 6,221,997 B1), for the reasons set forth in the previous office action filed 11/30/2007.

Applicant's arguments filed 04/30/2008 have been fully considered but they are not persuasive.

Applicants assert there is no disclosure or suggestion within Zhang of the reaction of a protein or any other bioactive agent with a multifunctional isocyanate compound and Zhang does not even mention what is meant by incorporation of proteins.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Clearly the examiner noted that Zhang while disclosing the peptide based urethane polymer may allow incorporation of proteins of interest such as cell attachment and/or growth factors but does not give any working examples, which is why the reference was combined with the other two other references in a 103(a) obviousness type of rejection. From the disclosures of Liptova and Woodhouse it would have been obvious to one of ordinary skill in the art that polyurethanes of Zhang could be conjugated to bioactive substances such as peptides and heparin.

Claims 1,3-4,7-12,15-16,19,25 and 69 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 7,264,823 B2, for the reasons set forth in the previous office action filed 11/30/2007.

Applicant's arguments filed 04/30/2008 have been fully considered but they are not persuasive.

Applicants assert that for the reasons set forth above for the 102(e) rejection over Beckaman the reference does not disclose or teach the claimed invention.

For the reasons noted above by the examiner Beckman is still an obviousness type double patenting rejection because as stated above applicant's attempted limitation that the isocyanate compound and bioactive agent are reacted in a solution with water is a product by process type of limitation. Since the claims are drawn to a composition the method to make the polyurethane does not alleviate the double patenting rejection over Beckman.

Conclusion

No claims are allowed at this time.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP §706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to James W. Rogers, Ph.D. whose telephone number is (571) 272-7838. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on (571) 271-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Michael G. Hartley/

Supervisory Patent Examiner, Art Unit 1618

<div>Application Number</div> <div></div>	Application/Control No.	Applicant(s)/Patent under Reexamination	
	10/759,904	BECKMAN ET AL.	
	Examiner	Art Unit	
	JAMES W. ROGERS	1618	